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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,713	10/22/2003	Timothy C. Thompson	PRO025/4-9CON2US	9759

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EXAMINER	
YAO, LEI	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,713	THOMPSON, TIMOTHY C.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *26-105* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment filed on 10/22/03 has been entered, in which claims 1-25 have been cancelled and claims 26-105 are added. Accordingly, the election/restrictions requirement dated 9/19/06 is vacated and replaced by the following action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 26-39, drawn to a method of treating a subject having neoplastic disorder comprising administering an anti-caveolin antibody to said patient, classified in class 424, subclass 130.1.

II. Claims 35, 40- 59, 66-85 and 98-104 method of treating a subject having neoplstic disorder comprising administering caveolin nucleic acid to said patient, classified in class 514, subclass 44.

It is noted that this inventive group contains duplicated claims. Amending to the claims or deleting the duplicated claims would be appreciated.

III. Claims 60-64, drawn to a method of treating a disorder comprising administering a composition that suppressed caveolin expression in the neoplastic cell, classified in class 435, subclass 4.

IV. Claims 65, drawn to a therapeutic composition comprising anti-caveolin agent in an amount to inhibit caveolin activity in a metastatic cell, classified in class 530, subclass 387.1.

V. Claims 86-97, and 105, drawn to a composition comprising an isolated nucleic acid, a population of expression vectors, wherein the vector express a caveolin nucleic acid, classified in class 536, subclass 23.1.

Inventions Group II/V, III/V, and I/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group V can be used to make a protein, as opposed to being used for treating a neoplastic disorder or cancer. Group IV, anti-caveolin agent, can be used for detecting the presence of the caveolin protein for diagnosing the disease, as opposed to being used for treating a neoplastic disorder or cancer. Searching the inventions of Groups II and V, III and V, I and IV, or all the group together would impose serious search burden. The inventions of Groups have a separate status in the art as shown by their different classifications. The search for the nucleic acid and the method of treating a disease using a polynucleotide are not coextensive. Prior art that teaches a nucleic acid would not necessarily be applicable to the method of using the nucleic acid for treating the neoplastic disease. Moreover, even if the polynucleotide product were known, the method of treating neoplastic disorder using the product may be novel and unobvious in view of the preamble or active steps.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I, II, and III are patentably distinct methods, which differ in the method steps and reagents used. The instant specification does not disclose these methods would be used together. Group I is directed to a method of treating a subject having neoplastic disorder comprising administering an anti-caveolin antibody. Group II is method for treating a subject having neoplastic disorder comprising administering nucleic acid. Group III is suppressed caveolin expression in the neoplastic cell in vitro. Each invention performs this function using a structurally and functionally divergent material, which are involved in different method steps and mode of operations. Because these inventions are distinct they have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, Therefore, restriction for examination purposes as indicated is proper.

Inventions VI and V are patentably distinct products.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Disease condition of neoplastic disorders listed in claim 27-30, 33 and 34.

b. RNA, DNA, or PNA.

c. Vector listed in claims 89.

d. CMV or MMTV promoter.

In the event that applicant elects any invention from I-III, applicant is required under 35 U.S.C. 121 to elect ONE single disclosed disease condition from **a)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect hyperplasia of prostate.

In the event that applicant elects invention II or III, applicant is further required under 35 U.S.C. 121 to elect ONE single disclosed species from **b)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect RNA.

In the event that applicant elects Inventions V, applicant is required under 35 U.S.C. 121 to elect ONE single disclosed species from **c)** and ONE single disclosed species from **d)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect retroviral vector and CMV promoter.

If applicants amend to the claims by adding species listed above to the claims in the elected invention, applicant is required to elect ONE species along with the elected invention in the response to the restriction requirement.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an

allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitation of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitation of an allowable product claim for that process invention to be rejoined.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution to require the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON A. FOLEY
SUPERVISORY PATENT EXAMINER